REMARKS

The Office Action mailed January 21, 2010 has been received and reviewed. Each of claims 1, 3, 5-8, 10, 12-15, 17 and 19-23 stands rejected. Claims 1, 8 and 15 have been amended herein. The support for these amendments can be found in the specification at paragraphs [0031]-[0034] and [0036]. Care has been exercised to introduce no new subject matter. Reconsideration of the above-identified application in view of the above amendments and the following remarks is respectfully requested.

Rejections based on 35 U.S.C. § 112

Claims 1, 3, 5-8, 10, 12-15, 17 and 19-23 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Office states the "claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." With regards to independent claims 1, 8 and 15, the Office regards the limitation of "determining from the hereditary information whether a parent of the person had the gene variant" as comprising new matter.

Applicants respectfully submit that claims 1, 8 and 15, have been amended to clarify the scope of the claims. In particular, the limitation of "determining from the hereditary information whether a parent of the person had the gene variant" has been removed from each of claims 1, 8 and 15. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. 112, first paragraph rejection of claims 1, 8 and 15. Additionally, as claims 3, 5, 7, 10, 12-14, 17 and 19-23 were rejected because they depend on the above rejected independent claims, Applicants respectfully request the withdrawal of the rejection to these claims as well.

Rejections based on 35 U.S.C. § 103

Title 35 U.S.C. § 103(a) declares that a patent shall not issue when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." In *Graham v. John Deere,* the Supreme Court counseled that an obviousness determination is made by identifying: the scope and content of the prior art; the level of ordinary skill in the prior art; the differences between the claimed invention and prior art references; and secondary considerations. *See Graham v. John Deere Co.*, 383 U.S. 1 (1966).

"In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious." MPEP § 2141.02(I) (emphasis in original) (citing *StratoFlex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983)). "All words in a claim must be considered in judging the patentability of that claim against the prior art." MPEP § 2143.03 (quoting *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (C.C.P.A. 1970)). Moreover, if an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. MPEP § 2143.03 (citing *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)).

"The examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness . . . . To reach a proper determination of obviousness, the examiner must step backward in time and into the shoes worn by the hypothetical 'person of ordinary skill in the art' when the invention was unknown and just before

it was made. In view of all factual information, the examiner must then determine whether the claimed invention 'as a whole' would have been obvious at that time to that person. *Id* (emphasis added). Knowledge of applicant's disclosure must be put aside in reaching this determination . . . . [I]mpermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art." MPEP § 2142.

"The key to supporting any rejection under 35 U.S.C. 103 is the **clear articulation of the reason(s)** why the claimed invention would have been obvious." MPEP § 2142 citing *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (U.S. 2007) (emphasis added), which notes that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. Moreover, the Federal Circuit has stated that "'rejections on obviousness **cannot be sustained with mere conclusory statements**; instead, there must be some **articulated reasoning** with some rational underpinning to support the legal conclusion of obviousness.'" MPEP § 2142 (emphasis added) (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). See also *KSR*, 127 S. Ct. at 1741 (quoting Federal Circuit statement with approval).

Claims 1, 3, 5-8, 10, 12-15, 17 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ichikawa (Internal Medicine, July 2000, vol. 39, no. 7, pp. 523-524, hereinafter Ichikawa) in view of Reinhoff et al. (U.S. Publication No. 2002/0049772, hereinafter Reinhoff) in view of Fey et al. (U.S. Publication No. 2002/0038227, hereinafter Fey) and further in view of Fiedotin et al. (U.S. Patent No. 7,509,263, hereinafter Fiedotin) and further in view of Harris ("Probabilistic belief networks for genetic counseling", Computer Methods and Programs in Biomedicine, May 1990, vol. 32, pp. 37-44, hereinafter Harris). As the combination of the Ichikawa, Reinhoff, Fey, Fiedotin and Harris references fail to teach or suggest all features of the rejected claims, Applicants respectfully traverse this rejection, as hereinafter set forth.

Independent claim 1 as amended herein is generally directed to a computer-implemented method for displaying information on one or more user interfaces regarding the likelihood a person has a gene variant indicative of an atypical event. The method includes the steps of: displaying a first user interface to a clinician, the user interface configured to display and receive clinical agent information including at least one identifier of a clinical agent; receiving from the user interface the clinician's inputs including at least one identifier of a clinical agent and a dosage of the clinical agent, wherein receiving includes receiving a selection of an entry in a listing of clinical agents on the first user interface and a selection of the dosage from a range of dosages recommended for the clinical agent associated with the selected entry; accessing a data structure to determine if a gene variant is known to be associated with one or more atypical events for the identifier of the clinical agent received from the clinician, wherein the data structure includes an agent-gene association table; inquiring if the person to whom the clinical agent is to be administered has a stored genetic test result value for the gene variant, wherein inquiring includes accessing an electronic medical record (EMR) of the person; accessing hereditary information for the person if the person does not have a genetic test result value for the genetic variant, the hereditary information being information that may be utilized to determine if the person has a predisposition for certain conditions, wherein the hereditary information is obtained from the EMR of the person; utilizing the hereditary information for the person to determine the likelihood the person has the gene variant; generating an output including information regarding the likelihood that the person has the gene variant indicative of an atypical event based on the hereditary information; and displaying a second user interface to the clinician, the user interface configured to display the output regarding the likelihood the person has the gene variant indicative of an atypical event for the identifier of the clinical agent

received from the clinician. *See generally, Specification* at ¶¶[0031]-[0036], [0039], [0041]-[0042]; FIG. 3, FIG. 6.

As amended herein, independent claim 8 is directed to a computer system embodied on one or more computer storage media having computer-executable instructions embodied thereon for displaying information on one or more user interfaces regarding the likelihood that the person has the gene variant indicative of an atypical event based on the hereditary information. The system includes: a first displaying component that displays a first user interface to a clinician, the user interface configured to display and receive clinical agent information including at least one identifier of a clinical agent; a receiving component that receives from the user interface the clinician's inputs including at least one identifier of a clinical agent and a dosage of the clinical agent, wherein receiving includes receiving a selection of an entry in a listing of clinical agents on the first user interface and a selection of the dosage from a range of dosages recommended for the clinical agent associated with the selected entry; a first accessing component for accessing a data structure to determine if a gene variant is known to be associated with one or more atypical events for the identifier of the clinical agent received from the clinician, wherein the data structure includes an agent-gene association table; an inquiring component that inquires if the person to whom the clinical agent is to be administered has a stored genetic test result value for the gene variant, wherein inquiring includes accessing an electronic medical record (EMR) of the person; a second accessing component for accessing hereditary information for the person if the person does not have a genetic test result value for the gene variant, the hereditary information being information that may be utilized to determine if the person has a predisposition for certain conditions, wherein the hereditary information is obtained from the EMR of the person; a utilizing component for utilizing the hereditary

information for the person to determine the likelihood the person has the gene variant; a generating component that generates an output including information regarding the likelihood that the person has the gene variant indicative of an atypical event based on the hereditary information; and a second displaying component for displaying a second user interface to the clinician, the user interface configured to display the output regarding the likelihood the person has the gene variant indicative of an atypical event for the identifier of the clinical agent received from the clinician. *See generally, Specification* at ¶¶[0031]-[0036], [0039], [0041]-[0042]; FIG. 3, FIG. 6.

Independent claim 15 as amended herein is generally directed to a computer storage medium containing instructions for a method for controlling a computer system for displaying information on one or more user interfaces regarding the likelihood that the person has the gene variant indicative of an atypical event based on the hereditary information. The method comprising the steps of: displaying a first user interface to a clinician, the user interface configured to display and receive clinical agent information including at least one identifier of a clinical agent; receiving from the user interface the clinician's inputs including at least one identifier of a clinical agent and a dosage of the clinical agent, wherein receiving includes receiving a selection of an entry in a listing of clinical agents on the first user interface and a selection of the dosage from a range of dosages recommended for the clinical agent associated with the selected entry; accessing a data structure to determine if a gene variant is known to be associated with one or more atypical events for the identifier of the clinical agent received from the clinician, wherein the data structure includes an agent-gene association table; inquiring if the person to whom the clinical agent is to be administered has a stored genetic test result value for the gene variant, wherein inquiring includes accessing an electronic medical record (EMR) of the

person; accessing hereditary information for the person if the person does not have a genetic test result value for the genetic variant, the hereditary information being information that may be utilized to determine if the person has a predisposition for certain conditions; utilizing the hereditary information for the person to determine the likelihood the person has the gene variant; generating an output including information regarding the likelihood that the person has the gene variant indicative of an atypical event based on the hereditary information; and displaying a second user interface to the clinician, the user interface configured to display the output regarding the likelihood the person has the gene variant indicative of an atypical event for the identifier of the clinical agent received from the clinician. *See generally, Specification* at ¶¶[0031]-[0036], [0039], [0041]-[0042]; FIG. 3, FIG. 6.

Independent claims 1, 8 and 15 have been amended herein to recite a clarification of the systems and methods for displaying information on one or more user interfaces regarding the likelihood a person has a gene variant indicative of an atypical event. In particular, the clarified process now recites the step of "receiving from the user interface the clinician's inputs including at least one identifier of a clinical agent and a dosage of the clinical agent, wherein receiving includes receiving a selection of an entry in a listing of clinical agents on the first user interface and a selection of the dosage from a range of dosages recommended for the clinical agent associated with the selected entry." The clarified process also recites the step of "accessing a data structure to determine if a gene variant is known to be associated with one or more atypical events for the identifier of the clinical agent received from the clinician, wherein the data structure includes an agent-gene association table." The clarified process also recites "accessing an electronic medical record (EMR) of the person" to whom the clinical agent is to be administered. The support for these amendments can be found in the specification at paragraphs

[0031]-[0034] and [0036]-[0040]. Advantageously, this process allows a clinician to incorporate the available genetic information of a person into the clinical decision making process.

By way of contrast with the invention of claims 1, 8 and 15 the Ichikawa reference describes a method of genetic screening where a particular single nucleotide polymorphism may be used to disclose severe side effects or proper dosage for a patient. *See generally, Ichikawa* at p. 523. The Ichikawa reference describes that a patient with an autosomal recessive trait for thiopurine S-methyl transferase (TMPT) deficiency may experience marked leucopenia when treated with immunosuppressants including azathioprine. *Id.* Applicants respectfully submit that the Ichikawa reference fails to teach or suggest features of claim 1, 8 and 15. For instance, the Ichikawa reference fails to teach or suggest receiving inputs from the clinician including an identifier of a clinical agent and a dosage of the clinical agent to be administered to the patient where, the clinician selects the clinical agent from a listing of clinical agents on a graphical user interface and where the clinician selects a specific dosage of the clinical agent from a range of dosages recommended for the clinical agent associated with the selected entry. The Ichikawa reference does not mention a computerized method of a clinician ordering a specific clinical agent and a specific dosage of the clinical agent and utilizing that information to provide a clinician with an output regarding the likelihood the patient has the gene variant associated with atypical events for the specified clinical agent.

The Office Action has acknowledged that the Ichikawa reference fails to teach the computer implemented aspects the invention of claim 1 including the aspect of accessing a data structure to determine if a gene variant is known to be associated with one or more atypical events. *See Office Action* at p. 7. The Office asserts that the Reinhoff reference teaches the above-mentioned features.

The Reinhoff reference is directed to a computer program product for separating individuals into subpopulations using a polymorphic profile in a networked environment. *See Reinhoff* at ¶ [0010]. In the Reinhoff reference, when a polymorphism is known to be associated with a response to a known treatment, this information may be used to allocate the most appropriate dose to subjects enrolled in a treatment study such as a clinical trial. *Id.* at ¶ [0057].

Applicants respectfully submit that the feature of a computerized method of receiving from a graphical user interface a clinician's inputs including at least one identifier of a clinical agent and a dosage of the clinical agent, where receiving includes receiving a selection of an entry in a listing of clinical agents on the first user interface and a selection of the dosage from a range of dosages recommended for the clinical agent associated with the selected entry, as described in the invention of claims 1, 8 and 15 is also absent from the Reinhoff reference. Rather, the Reinhoff reference discloses a computer program product that allows for comparing an individual's polymorphic profile with a plurality of polymorphic profiles to assist in performing clinical trials by ascertaining whether a particular nucleic acid variation affects the efficacy of a pharmaceutical. *Id.* at ¶¶ [0011]-[0014]. Nowhere does Reinhoff mention, receiving a clinician's order for a specific clinical agent and a specific dosage of the clinical agent and automatically utilizing that information to provide the clinician with an output regarding the likelihood the patient has the gene variant associated with atypical events for the specified clinical agent.

Furthermore, Reinhoff is silent on accessing an agent-gene association table to determine if a gene variant is known to be associated with atypical events for the specific clinical agent identified by the clinician and accessing the electronic medical record of the person to whom the clinical agent is to be administered to determine in the person possesses the gene

variant. The Reinhoff reference merely describes identifying a "susceptibility locus in individuals using genetic screening methods to assess an individual's risk of certain diseases." *Id.* at ¶ [0010]. The genetic screening methods in the Reinhoff reference consist of genetic tests involving using polymerase chain reaction (PCR) and other polymerase driven amplification assays to determine an individual's polymorphic profile. *See generally, id.* at ¶¶ [0027]-[0038]. Accordingly, Applicants submit that the Ichikawa reference in view of the Reinhoff reference fails to teach or suggest all the limitations of the independent claims 1, 8 and 15.

Applicants respectfully submit that the Fey reference fails to cure the deficiencies of the Ichikawa and Reinhoff references. The Fey reference describes a centralized health screening and management system. *See Fey* at [0020]. In Fey, data and test results are transmitted to a centralized data management system for analysis and storage in a manner that is accessible for report generation and aggregate information analysis. *Id.* The Fey reference does not disclose receiving from a graphical user interface a clinician's inputs including at least one identifier of a clinical agent and a dosage of the clinical agent, where receiving includes receiving a selection of an entry in a listing of clinical agents on the first user interface and a selection of the dosage from a range of dosages recommended for the clinical agent associated with the selected entry, as described in the invention of claims 1, 8 and 15.

Additionally, Fey is silent on accessing an agent-gene association table to determine if a gene variant is known to be associated with atypical events for the specific clinical agent identified by the clinician and accessing the electronic medical record of the person to whom the clinical agent is to be administered to determine in the person possesses the gene variant. The Fey reference merely discusses storing health data in a manner that is accessible. Accordingly, Applicants submit that the Ichikawa reference in view of the Reinhoff reference

and further in view of the Fey reference, fails to teach or suggest all the limitations of the independent claims 1, 8 and 15.

Applicants respectfully submit that the feature of receiving from a graphical user interface a clinician's inputs including at least one identifier of a clinical agent and a dosage of the clinical agent, where receiving includes receiving a selection of an entry in a listing of clinical agents on the first user interface and a selection of the dosage from a range of dosages recommended for the clinical agent associated with the selected entry, as described in the invention of claims 1, 8 and 15 is also absent from the Fiedotin reference. The Fiedotin reference describes a method for providing physicians access to current health care industry information including formulary data, and clinical and practice management information at the point of care on a handheld electronic device. *See Fiedotin* at Abstract. In Fiedotin, health care data is compiled from various sources such as clinical databases, the internet. *Id.* at col. 9 lines 27-29. The health care data includes information such as dosing, co-payment, drug pricing, drug-drug reaction and adverse reaction information. *Id.* at lines 30-35. Nowhere does Fiedotin mention receiving from the clinician an identifier of a clinical agent and a dosage of the clinical agent, via receiving a selection of an entry in a listing of clinical agents on a graphical user interface and a selection of the dosage from a range of dosages recommended for the clinical agent associated with the selected entry. Furthermore, Fiedotin is silent on accessing an agent-gene association table to determine if a gene variant is known to be associated with atypical events for the specific clinical agent identified by the clinician and accessing the electronic medical record of the person to whom the clinical agent is to be administered to determine in the person possesses the gene variant. Rather, Fiedotin merely describes a method for distributing general medical information stored on a computer system to a physician via a handheld

computing device. Accordingly, Applicants submit that the Ichikawa reference in view of the Reinhoff reference and further in view of the Fey and Fiedotin references, fails to teach or suggest all the limitations of the independent claims 1, 8 and 15.

Applicants respectfully submit that the feature of receiving from a graphical user interface a clinician's inputs including at least one identifier of a clinical agent and a dosage of the clinical agent, where receiving includes receiving a selection of an entry in a listing of clinical agents on the first user interface and a selection of the dosage from a range of dosages recommended for the clinical agent associated with the selected entry, as described in the invention of claims 1, 8 and 15 is also absent from the Harris reference. Harris describes a computer program which uses belief networks to calculate risks of inheriting genetic disorders. *See Harris* Abstract. In Harris, genotypes are calculated for a family with a single-gene inherited disorder utilizing family tree pedigrees showing the incidence of a particular genetic disorder in a family. *Id.* at pg. 38. Harris does not describe receiving from the clinician an identifier of a clinical agent and a dosage of the clinical agent, via receiving a selection of an entry in a listing of clinical agents on a graphical user interface and a selection of the dosage from a range of dosages recommended for the clinical agent associated with the selected entry, as described in the invention of claims 1, 8 and 15.

In addition, Harris is silent accessing an agent-gene association table to determine if a gene variant is known to be associated with atypical events for the specific clinical agent identified by the clinician and accessing the electronic medical record of the person to whom the clinical agent is to be administered to determine in the person possesses the gene variant. In Harris the consultand or person who presents for genetic counseling receives the probabilities that their *prospective offspring* will inherit a genetic disorder. In contrast, in the invention of

claims 1, 8 and 15, the clinician treating the consultand utilizes information regarding the consultand's parents to determine the likelihood the consultand has the gene variant. Accordingly, Applicants submit that the Ichikawa reference in view of the Reinhoff reference and further in view of the Fey, Fiedotin and Harris references, fails to teach or suggest all the limitations of the independent claims 1, 8 and 15.

As the Ichikawa reference in view of the Reinhoff reference and further in view of the Fey, Fiedotin and Harris references fails to teach or suggest all the limitations of the independent claims 1, 8 and 15, a *prima facie* case of obviousness has not been made for independent claims 1, 8 and 15 with respect to these references. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of these claims. Further, as claims 5-7, 10, 12-14, 17 and 19-21 depend directly or indirectly from amended independent claims 1, 8 and 15, Applicants request withdrawal of the rejection of these claims as well.

CONCLUSION

For at least the reasons stated above, claims 1, 3, 5- 8, 10, 12-15, 17, and 19-23 are now in condition for allowance. Applicants respectfully request withdrawal of the pending rejections and allowance of the claims. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned – 816-474-6550 or ajthompson@shb.com (such communication via email is herein expressly granted) – to resolve the same. It is believed that no fee is due, however, the Commissioner is hereby authorized to charge any amount required to Deposit Account No. 19-2112.

Respectfully submitted,

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